HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Sucraid (sacrosidase)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Sucraid oral solution, approved by the FDA in 1998, is an enzyme replacement therapy indicated for congenital sucrase-isomaltase deficiency (CSID). CSID, an inherited metabolic disorder, is characterized by a complete or almost complete lack of endogenous sucrase activity, a very marked reduction in isomaltase activity, a moderate decrease in maltase activity, and normal lactase levels. This condition reduces the ability to digest food containing sugars or starches.
The sacrosidase enzyme (Sucraid) is derived from baker's yeast and acts as a substitute for the endogenous sucrase digestive enzyme. Sucrase is produced in the small intestine and hydrolyzes the disaccharide sucrose into its component monosaccharides, glucose and fructose. When sucrase is absent (like in CSID), sucrose is not metabolized. Unhydrolyzed sucrose and starch won't be absorbed from the intestine, and their presence may lead to osmotic retention of water which can result in diarrhea, the primary symptom of CSID. Chronic malabsorption of disaccharides can lead to malnutrition. Sucrase does not replace the deficient isomaltase, therefore certain starches may still not be metabolized and patients can still have symptoms.

Sucraid (sacrosidase) will be considered for coverage when the following criteria are met:

Congenital Sucrase-Isomaltase Deficiency (CSID)

For **initial** authorization:

1. Member is at least 5 months of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist, endocrinologist, or dietician/nutritionist; AND
3. Member has a diagnosis of CSID confirmed by at least one of the following methods:
   a) Small bowel biopsy assayed for activity of disaccharidases
   b) C13 (carbon-13) breath test
   c) Genetic testing (showing SI gene mutation); AND
4. Member has inadequate relief from attempting a sucrose/starch restricted diet (i.e., continued chronic diarrhea); AND
5. Member does NOT have acquired/secondary sucrase-isomaltase deficiency (e.g., due to Celiac disease).
6. **Dosage allowed/Quantity limit:**
   Weight 15 kg or less: 1 mL (8,500 International Units) orally with each meal or snack
   Weight >15 kg: 2 mL (17,000 International Units) orally with each meal or snack
   QL: 2 bottles (118 mL x 2) per 28 days OR 150 two-mL single use containers (1 carton) per 30 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must document improvement of CSID symptoms (i.e., diarrhea, gas, bloating, cramps, vomiting).

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Sucraid (sacrosidase) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/29/2022	New policy for Sucraid created.
07/01/2024	Clarified that biopsy is used for enzyme activity assays.

References:

1. Sucraid [prescribing information]. QOL Medical, LLC; 2023.
2. Treem WR, McAdams L, Stanford L, Kastoff G, Justinich C, Hyams J. Sacrosidase therapy for congenital sucrase-isomaltase deficiency. *J Pediatr Gastroenterol Nutr*. 1999;28(2):137-142. doi:10.1097/00005176-199902000-00008
3. Treem WR. Clinical aspects and treatment of congenital sucrase-isomaltase deficiency. *J Pediatr Gastroenterol Nutr.* 2012;55 Suppl 2:S7-S13. doi:10.1097/01.mpg.0000421401.57633.90
4. Robayo-Torres CC, Opekun AR, Quezada-Calvillo R, et al. 13C-breath tests for sucrose digestion in congenital sucrase isomaltase-deficient and sacrosidase-supplemented patients. *J Pediatr Gastroenterol Nutr*. 2009;48(4):412-418. doi:10.1097/mpg.0b013e318180cd09

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